

Appl. No. : 10/735,481
Filed : December 12, 2003

REMARKS

Claims 2 and 33 have been cancelled without prejudice. Claims 6, 31, 35, 41 and 47 are withdrawn. Claims 37, 43, and 48 are under consideration. Applicant understands that upon allowance of the peptide claims, the method claims 31 and 35 may be considered for rejoinder. Applicant also understands that upon allowance of claims to the elected species of SEQ ID NO: 2, the withdrawn claims 6, 35, 41 and 47 drawn to non-elected species of SEQ ID NO: 3 will be rejoined and considered for patentability.

The Examiner has maintained the rejection of Claims 2, 37, 43 and 48 under 35 USC §102(b) as being allegedly anticipated by Akerblom et al. (USP 5,834,192).

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Akerblom et al. describe an HCAP protein, 110 aa long, suggested to be involved in cancer-induced cachexia. Akerblom et al. does not disclose an isolated antimicrobially active peptide consisting of a fragment of the C-terminal of dermcidin protein of SEQ ID NO: 1, said fragment comprising a maximum of 50 contiguous amino acids of said C-terminal. The peptides, including the one of SEQ ID NO: 2, were experimentally shown to have antimicrobial effects. Akerblom et al. do not teach such peptides. Instead, Akerblom teaches a full-length 110 aa or a mature 90 aa long protein that was found to be associated with cachexia. The Examiner further stated that there is nothing on the record via a side-by-side comparison to show that the peptide of the prior art would not have the same activity of the instantly claimed peptide, and that because amino acid residues 63-110 are present in the protein of Akerblom, such protein would inherently have antimicrobial activity. The issue here is not if the full length 110 aa or mature 90 aa protein of Akerblom would inherently be antimicrobial, but that Akerblom does not teach the claimed peptides.

Therefore, Akerblom et al. does not anticipate currently amended Claims 37, 43 and 48, and the rejection of these claims under 35 USC §102(b) should be withdrawn.

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Written description

The Examiner has maintained the rejection of Claim 2 under 35 USC §112, first paragraph as allegedly containing new matter. In view of cancellation of Claim 2 and amendments to Claim 48, this rejection is now moot.

The Examiner has rejected Claim 48 under 35 USC §112, first paragraph as failing to comply with the written description requirement. Claim 48 has been amended to now recite an isolated antimicrobially active peptide consisting of a fragment of the C-terminal of dermcidin protein of SEQ ID NO: 1, said fragment comprising a maximum of 50 contiguous amino acids of said C-terminal. The Specification provides two species of the claimed genus: SEQ ID NO: 2 – 48 contiguous amino acids from the C-terminal of SEQ ID NO: 1; and SEQ ID NO: 3 – 47 contiguous amino acids from the C-terminal of SEQ ID NO: 1. A skilled artisan would have no difficulty figuring out which end of a 110-amino acid protein is its C-terminal, or how to make the claimed peptides and test them for antimicrobial activity, based on the teachings in the Specification as filed and the state of the art at the time the invention was made. The inventors were the first ones to discover the antimicrobial activity of fragments of the dermcidin protein consisting of a maximum of 50 amino acids. Therefore, Applicant asserts that the claimed antimicrobially active peptides are fully supported by the Specification as filed, and the rejection of Claim 48 under 35 USC §112, first paragraph should be withdrawn.

Definiteness

The Examiner has rejected Claims 2, 37, 43 and 48 under 35 USC §112, second paragraph, as being allegedly indefinite for reciting “substantially in isolation” and “consisting essentially of a fragment of the C terminal”. Applicant disagrees. But in view of cancellation of Claim 2 and amendments to Claims 37, 43 and 48, this rejection is now moot. Furthermore, the metes and bounds of a peptide having a maximum of 50 contiguous amino acids from a defined sequence and having a specific function are very definite to a skilled artisan. Therefore, this rejection should be withdrawn.

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CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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